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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,010	01/10/2001	Steven H. Bass	02-100620US	2748

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MAXYGEN, INC.
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EXAMINER

CALAMITA, HEATHER

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/760,010	Applicant(s) BASS ET AL.	
	Examiner Heather G. Calamita, Ph.D.	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 300-427 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 300-427 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/22/01, 8/21/03, 11/22/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 300-325, 329-345, 349-365 and 366-427 are rejected under 35 U.S.C. 102(e) as being anticipated by Cohen et al. (USPN 5,945,522, 08/31/1999).

Cohen et al. teach (claims 300, 320, 340, 360, 381, 391, 401 and 411) a system for diversity generation generating diverse nucleic acids, said system comprising:

- (a) a computer containing data that corresponds to one or more sequences selected from the group consisting of one or more target sequences for diversity generation and one or more diverse sequences (see col. 53, line 49, a thermocycler is inherently coupled to a computer);
- (b) an array (see col. 37, lines 56-58);
- (c) an automated liquid handler operably coupled to (a) and (b) for dispensing nucleic acids into the array (see col. 37 lines 23-27);

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(d) a thermocycler, incubator and recombination module operably coupled to the array for generating one or more diverse nucleic acids (see col. 35 line 49, col. 37, line 36 and col. 39 lines 6-13, respectively).

(e) a product production module for automatically generating polypeptide product from the one or more diverse nucleic acids (see col. 39 lines 6-9);

(f) a product purification module operably coupled to (e) for purifying the polypeptide product from the product production module, either partially or substantially to homogeneity (see col. 40 lines 21-34);

(g) a detector for identifying polypeptide product having a desired property (see col. 40 lines 53-43 and 55-67).

With regard to claims 301, 321, 341, 361, 382, 392, 402 and 412, Cohen et al. teach further comprising an automated oligonucleotide synthesizer operably coupled to (c) (see col. 37 lines 65-66). With regard to claims 302, 322, 342, 362, 383, 393, 403 and 413, Cohen et al. teach further comprising an automated fragmentation module operably coupled to (c) for producing fragmented nucleic acids (see col. 30 lines 51-65). With regard to claims 303, 323, 343, 363, 384, 394, 404 and 415, Cohen et al. teach the system generates one or more diverse nucleic acids by assembly of oligonucleotides (see col. 30 lines 51-65, col. 37 lines 65-66). With regard to claims 304, 324, 344 and 364, Cohen et al. teach the automated fragmentation module utilizes a directed primer (see col. 30 lines 51-65). With regard to claims 305, 325, 345, 365, 385, 395, 405 and 414, Cohen et al. teach further comprising a means for fragment purification (see col. 38 lines 58-62). With regard to claims 311, 329, 331, 349, 351, 369, 370 and 372, Cohen et al. teach further comprising a physical array (see col. 37 lines 56-58). With regard to claims 310, 330, 350 and 371, Cohen et al. teach the product production module conducts in vitro transcription and in vitro translation of diverse nucleic acids to generate a polypeptide product (see col. 38 lines 65-67, col. 39 lines 6-14). With regard to claims 312, 332, 352 and 373, Cohen et al. teach the array

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is a microwell plate (see col. 37, lines 56-58). With regard to claims 313, 333, 353 and 374, Cohen et al. teach the array is a logical array (see col. 37 lines 56-58). With regard to claims 314-316, 334-336, 354-356, 375-377, 386, 387, 396, 397, 406, 407, 416 and 417, Cohen et al. teach the computer contains data that correspond to one or more diverse sequences and the system generates one or more diverse nucleic acids corresponding to the data (see col. 37 lines 23-26). With regard to claims 317-319, 337-339, 357-359, 378-380, 388-390, 398-400, 408-410, 418-420, Cohen et al. teach a second liquid handler for diluting the diverse nucleic acids in an array (capillary electrophoresis, see col. 44 lines 13-14).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 326-328, 346-348, 366-368 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (USPN 5,945,522, 08/31/1999) in view of Singh (US 2001/0055763 A1, 12/27/2001).

The teachings of Cohen et al. are described previously.

Cohen et al. do not teach a liquid array.

Singh teaches a liquid array (see paragraph 0009 line3).

It would have been prima facie obvious to utilize the system for generating diverse nucleic acids as taught by Cohen et al. (USPN 5,945,522, 08/31/1999) with the liquid array as taught by Singh (US 2001/0055763 A1, 12/27/2001) since Singh notes "Various protocols may be employed with the liquid arrays and various detection schemes may be employed for

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deconvoluting the plurality of solid moieties resulting from the operation (see paragraph 0009 lines 20-23).” An ordinary practitioner would have been motivated to use the system for generating diverse nucleic acids as taught by Cohen et al. (USPN 5,945,522, 08/31/1999) with the liquid array as taught by Singh (US 2001/0055763 A1, 12/27/2001) in order to perform a number of simultaneous events, utilizing various protocols, in a single reaction vessel with a complex sample.

4. Claims 421-427 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (USPN 5,945,522, 08/31/1999) in view of Nova et al. (USPN 6,284,459, 09/04/2001).

The teachings of Cohen et al. are described previously.

Cohen et al. do not teach a bar code.

Nova et al. teach a bar code (see col. 7 lines 51-65).

It would have been prima facie obvious to utilize the system for generating diverse nucleic acids as taught by Cohen et al. (USPN 5,945,522, 08/31/1999) with the bar code as taught by Nova et al. (USPN 6,284,459, 09/04/2001) since Nova et al. note “The memories include electronic and optical storage media and also include optical memories, such as bar codes and other machine readable codes. By virtue of this combination, molecules and biological particles, such as phage and viral particles and cells that are in proximity or in physical contact with the matrix combination can be labeled by programming the memory with identifying information (see abstract).” An ordinary practitioner would have been motivated to use the system for generating diverse nucleic acids as taught by Cohen et al. (USPN 5,945,522, 08/31/1999) with the bar code as taught by Nova et al. (USPN 6,284,459, 09/04/2001) in order to permanently scribe information on the matrix for quick retrieval at a later time.

Summary

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5. No claims are allowed.

Correspondence

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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PRIMARY EXAMINER
2/5/05